



UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

SERIAL NUMBER REQUEST DATE

FIRST NAMED APPLICANT

ATTORNEY DOCKET NO.

P-107,738

7/10/03

GREGORY E. AMIDON, ET AL.

01681/2

Title:

SUSTAINED-RELEASE TABLET COMPOSITION OF
PRAMIPEXOLE

Art Unit

Paper Number

Correspondence Address:

James C. Forbes

PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT

75 MARYVILLE CENTRE DRIVE

5TH FLOOR, MAIL ZONE 1006

ST. LOUIS MO 63141

*orig in file set
underneath*

Licensee under 35 U.S.C. 184 is hereby granted to file in any foreign country a patent application and any amendments thereto corresponding to the subject matter of this U.S. application identified above and/or any material accompanying the petition. This license is conditioned upon modification of any applicable secrecy order and is subject to revocation without notice.

License Number: 530,990

Grant Date: 11-Jul-03

Approved

[Signature]

for Commissioner of Patents and Trademarks

This license empowers the filing, the causation and the authorization of the filing of a foreign application or applications on the subject matter identified above, subsequent forwarding of all duplicate and formal papers and the prosecution of such application or applications.

This license is granted under 37 CFR 5.15(a).

This license is to be retained by the licensee and may be used at anytime on or after the date thereof. This license is not retroactive unless specifically indicated.

The grant of this license does not in any way lessen the responsibility of the licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations, especially with respect to certain countries, of other agencies, particularly the Department of the Treasury; Office of Munitions Control, Department of State (with respect to Arms, Munitions and Implements of War); the Bureau of Trade Regulation, Office of Export Administration, Department of Commerce; and the Department of Energy.

LICENSE FOR FOREIGN FILING

[Title 35, United States Code (1952) Sections 184, 185, 186]

Best Available Copy

Gawlik, Susan B. [LGL/1820]

From: Susie Kapeleris [skapeleris@landonstark.com]
Sent: Monday, July 14, 2003 1:15 PM
To: Gawlik, Susan B. [LGL/1820]
Subject: RE: SEE BELOW



29188.pdf

Ms. Gawlik,

Attached please find a copy of the Foreign Filing Licenses just granted. An invoice and hard copies will follow in the mail. Please contact us if you have any questions or concerns.

Thanks and Best Regards,

Susie Kapeleris
Landon Stark Cantwell & Paxton
2011 Crystal Drive - Suite 210
Arlington, VA 22202
703 486 1150
703 892 4510 (fax)
Orders & Inquiries: mail@landonstark.com
Website: www.landonstark.com or www.cantwellpaxton.com

We are pleased to announce the merger of Landon & Stark and Cantwell & Paxton

Patent Abstract

Identifying family number: 01681

Title: Sustained Release Tablet Composition of Pramipexole

Priority date: 25 July 2002

Inventors: Gregory E. Amidon, Loksidh D. Ganorkar, John M. Heimlich, Ernest J. Lee, Robert M. Noack, Joseph P. Reo, Connie J. Skoug

Originating site of invention: Kalamazoo, MI

Primary therapeutic area: Neurodegeneration

Secondary therapeutic area: Pharmaceutical Sciences

Primary claim type: Formulation

Target: Dopamine D₂ receptor (agonist)

Summary of the invention/indication:

Sustained-release tablets of a water-soluble salt of PRAMIPEXOLE comprise a hydrophilic polymer and a starch selected to have high tensile strength. The tablets exhibit improved mechanical stability and strength, resulting in improved tableting efficiency on a manufacturing scale.

Broadest coverage:

A pharmaceutical tablet comprising a water-soluble salt of PRAMIPEXOLE dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least about 0.15 kN cm⁻² at a solid fraction representative of the tablet.

Specific embodiment:

A tablet as above comprising 0.3 to 5 mg PRAMIPEXOLE as the dihydrochloride salt. Possible MIRAPEX SR product.

Granted claims/specific issues/other relevant information:

Related to 00787, 01132, 01645.

Does this case involve a license or collaboration: No, but check Boehringer Ingelheim agreement.

Responsible agent/attorney: Jim Forbes - Skokie, IL

Outside counsel: None

**United States Patent and
Trademark Office**

Case No. 01645/2 JCF

Inventor	Lee, et al.
Serial No.	
Reg. Date/Filing Date	July 10, 2003
Received as of date stamped	
Petition for expedited License for Foreign Exporting and Filing in triplicate; Application for Letters Patent; Post Card	

RECEIVED
JUL 10 2003
LICENSING & REVIEW

**United States Patent and
Trademark Office**

Case No. 00787/3 JCF

Inventor	Ganorkar, et al.
Serial No.	
Reg. Date/Filing Date	July 10, 2003
Received as of date stamped	
Petition for Expedited License for Foreign Exporting and Filing in triplicate; Application for Letters Patent; Post Card	

RECEIVED
JUL 10 2003
LICENSING & REVIEW

**United States Patent and
Trademark Office**

Case No. 01681/2 JCF

Inventor	Amidon, et al.
Serial No.	
Reg. Date/Filing Date	July 10, 2003
Received as of date stamped	
Petition for Expedited License for Foreign Exporting and Filing in triplicate; Application for Letters Patent; Post Card	

RECEIVED
JUL 10 2003
LICENSING & REVIEW

**United States Patent and
Trademark Office**

Case No. 01132/4 JCF

Inventor	Amidon, et al.
Serial No.	
Reg. Date/Filing Date	July 10, 2003
Received as of date stamped	
Petition for expedited License for Foreign Exporting and Filing in triplicate; Application for Letters Patent; Post Card	

RECEIVED
JUL 10 2003
LICENSING & REVIEW

Gawlik, Susan B. [LGL/1820]

From: Chris Robbins
Sent: Thursday, July 10, 2003 1:36 PM
To: Gawlik, Susan B. [LGL/1820]
Subject: RE: 00787/3, 01132/4, 01645/2, 01681/2

Dear Ms. Gawlik,

Please note that our name and address have changed—see new contact information below. We received your four expedited license applications, and we have delivered them to the Office of Licensing & Review. Attached please find the stamped receipt post cards. As soon as the licenses are issued, we will email them to you. Hard copies will be delivered via regular mail. Please contact us if you have any questions.

Regards,

Chris Robbins
Senior Researcher
Landon Stark Cantwell & Paxton
2011 Crystal Drive - Suite 210
Arlington, VA 22202
703 486 1150
703 892 4510 (Fax)
Orders & Inquiries: mail@landonstark.com
Website: www.landonstark.com or www.cantwellpaxton.com

We are pleased to announce the merger of Landon & Stark and Cantwell & Paxton

01681/2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Amidon, et al) ATTORNEY DOCKET NO.: 01681/2
SERIAL NO.: n/a) GROUP ART UNIT: n/a
FILED: n/a) EXAMINER: n/a
TITLE: SUSTAINED-RELEASE TABLET COMPOSITION OF PRAMIPEXOLE
DATE: July 10, 2003

Assistant Commissioner for Patents
Washington, DC 20231
Attention: Security Group 220, Licensing and Review

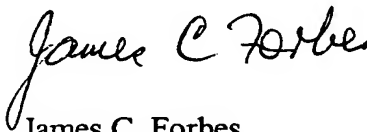
Sir:

PETITION FOR EXPEDITED LICENSE FOR FOREIGN EXPORTING AND FILING
UNDER 37 CFR §5.12(b)

Applicant hereby petitions for a license for foreign exporting and filing for subject matter related to the patent application referenced above. **THIS SUBJECT MATTER IS RELATED TO PHARMACEUTICAL COMPOSITIONS AND IS CLEARLY OF NO CONCERN FROM A SECURITY STANDPOINT.**

- ☒ Additional related U.S. applications are identified on the enclosed sheet.
☒ Applicant further petitions for expedited handling of this license.
☒ Please charge the sum of \$130, or such greater or lesser amount as may be required under 37 CFR §5.12(b) and §1.17(h), to Deposit Account No. 19-1025.

Respectfully submitted,



James C. Forbes
Agent for Applicant
Registration No. 39,457
Tel. (847) 581-6090

Address correspondence to:

Pharmacia Corporation
Global Patent Department
575 Maryville Centre Drive
5th Floor, Mail Zone 1006
St Louis, MO 63141

Encl: Additional related U.S. application information
Triplicate petition
Subject matter/patent application for which license is sought

01681/2

PETITION FOR EXPEDITED LICENSE FOR FOREIGN EXPORTING AND FILING
UNDER 37 CFR §5.12(b)

ADDITIONAL RELATED U.S. APPLICATION INFORMATION

<u>Serial No.</u>	<u>Filing date</u>	<u>Pending/abandoned</u>
60/398,427	July 25, 2002	Pending
60/398,447	July 25, 2002	Pending

U.S. Provisional Application titled "Sustained-release tablet composition of pramipexole" by G.E. Amidon et al., filed June 18, 2003, attorney docket no. 01681/1/US (no serial no. available)

Best Available Copy



**** WELCOME TO ****
EDGEBROOK POSTAL STORE
CHICAGO, IL 60646-4106
07/24/03 04:19PM

Store USPS 112
Wkstn sys5003 Cashier KJ3190
Cashier's Name ELIZABETH
Stock Unit Id WINLOMAX
PO Phone Number 773-774-2811
USPS # 1615420461

1. Exp. Mail PO-ADD 22313 0.00
Destination: 7.70oz
Weight: Affixed
Postage Type: -13.65
Affix Post.: 13.65
Total Cost: 13.65
Base Rate: 13.65

01681/2/US

2. Exp. Mail PO-ADD 22313 0.00
Destination: 9.70oz
Weight: Affixed
Postage Type: -17.85
Affix Post.: 17.85
Total Cost: 17.85
Base Rate: 17.85

01681/2/US

Subtotal 0.00
Total 0.00

Number of Items Sold: 2

THANK YOU
PLEASE COME AGAIN
GOD BLESS AMERICA
BE SAFE

10/626/66

929-03 per telecom
PTO (703)-308-0910

10/626, 166 724-03



ER 078630429 US



UNITED STATES POSTAL SERVICE®

Post Office To Addressee

Customer Copy
Label 11-B September 2002

ORIGIN (POSTAL USE ONLY)			
PO ZIP Code 00646	Day of Delivery <input type="checkbox"/> Next <input type="checkbox"/> Second	Flat Rate Envelope <input type="checkbox"/>	
Date 7-24-03	<input type="checkbox"/> 12 Noon <input type="checkbox"/> 3 PM	Postage \$ 13.65	
Mo. Day Year 07 24 03	<input type="checkbox"/> 2nd Day <input type="checkbox"/> 3rd Day	Return Receipt Fee	
Time In <input type="checkbox"/> AM <input checked="" type="checkbox"/> PM	Military <input type="checkbox"/>	COD Fee	
Weight 8 lbs.	Int'l Alpha Country Code	Insurance Fee	
No Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday	Acceptance Clerk Initials PZ	Total Postage & Fees \$ 13.65	
FROM: (PLEASE PRINT) PHARMACIA CORPORATION Corporate Patent Department P O Box 5110 Chicago IL 60680			
PHONE (847) 581-0000			
01681/2/US JCF			

DELIVERY (POSTAL USE ONLY)		
Delivery Attempt	Time	Employee Signature
Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	
Delivery Attempt	Time	Employee Signature
Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	
Delivery Date	Time	Employee Signature
Mo. Day	<input type="checkbox"/> AM <input type="checkbox"/> PM	
CUSTOMER USE ONLY		
PAYMENT BY ACCOUNT Express Mail Corporate Acct. No. _____ Federal Agency Acct. No. or Postal Service Acct. No. _____ <input type="checkbox"/> NO DELIVERY <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday		
<input type="checkbox"/> WAIVER OF SIGNATURE (Domestic Only) Additional merchandise insurance is void if waiver of signature is requested. I wish delivery to be made without obtaining signature of addressee or addressee's agent (if delivery employee judges that article can be left in secure location) and I authorize that delivery employee's signature constitutes valid proof of delivery.		
Customer Signature _____		

TO: (PLEASE PRINT)		PHONE (
COMMISSIONER FOR PATENTS MAIL STOP PATENT APPLICATION P O Box 1450 Alexandria VA 22313-1450		
2	2	3
1	3	+
1	4	5
0		
ZIP + 4		

FOR PICKUP OR TRACKING CALL 1-800-222-1811

www.usps.com



PRESS HARD. You are making 3 copies.

**United States Patent and
Trademark Office**

Case No. 01681/2 JCF

Inventor	Amidon, et al.
Serial No.	
Reg. Date/Filing Date	July 10, 2003
Received as of date stamped	
Petition for Expedited License for Foreign Exporting and Filing in triplicate; Application for Letters Patent; Post Card	

RECEIVED
JUL 10 2003
LICENSING & REVIEW